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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,615	06/29/2001	Gerald W. Fischer	07787.0041-01	5776

22852 7590 01/15/2003

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	14

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/893,615	Fischer et al
Examiner	**Art Unit**
Portner	1645

-- *The MAILING DATE of this communication appears on the cover sh et with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 1, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *32-44* is/are pending in the application.

4a) Of the above, claim(s) *41* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *32-40 and 42-44* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *32-44* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *8,12*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other.

DETAILED ACTION

Claims 1-31 have been canceled.

Claims 32-44 are pending; claims 32-40, 42-44 are under consideration.

Election/Restriction

1. Claim 41 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

2. Applicant's election with traverse of Group I, claims 32-40 and 42-44 in Paper No. 7, dated June 29, 2001 is acknowledged. The traversal is on the ground(s) that "Applicants do not believe that there is any undue burden on the Office to search this subject matter of Group I". These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1)independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I and II are drawn to distinct inventions which are related as separate products capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. Active and Passively pharmaceutical compositions comprise structurally and functionally different molecules and function in vivo by differing mechanisms of action. In the instant case a burden has been established in showing that the inventions of Groups I, and II classified separately necessitating different searches of issued US Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example immunotherapy with antibodies delivers a distinctly different composition from a peptide antigen composition to a patient. Additionally, it is submitted that the inventions of Groups I, and II have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

Priority

3. Applicant's claim to priority under 35 U.S.C. 119(e) is herein acknowledged.

Information Disclosure Statement

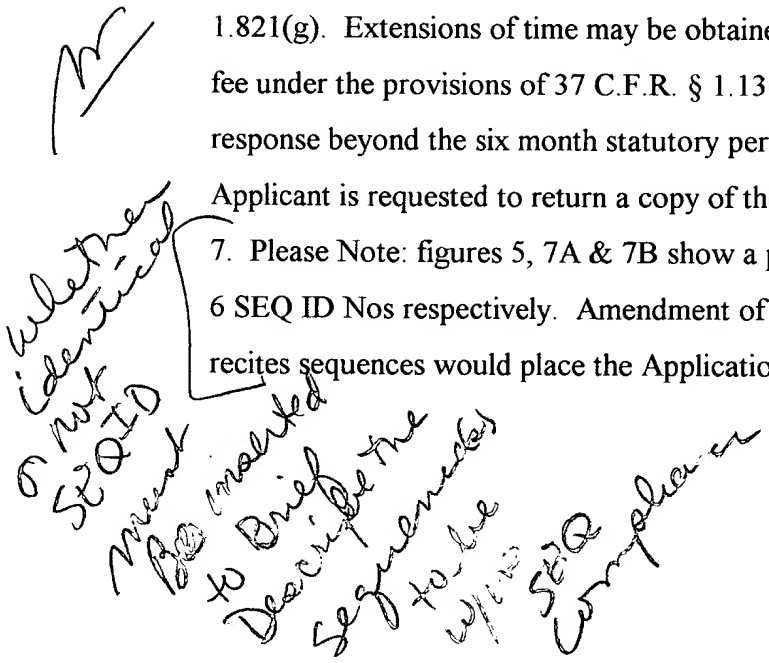
4. The information disclosure statement filed June 29, 2001 and October 7, 2002 have been considered as to the merits prior to first action. ACW 7/14/2003

Sequence Letter

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

6. APPLICANT IS GIVEN the time period set for THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

7. Please Note: figures 5, 7A & 7B show a plurality of sequences that are only identified by 4 and 6 SEQ ID Nos respectively. Amendment of the Brief Description of the Drawings to identify the recites sequences would place the Application into sequence compliance.



Brief Description of the Drawings

8. The Brief Description of the drawings are objected to because the description of Figures 6A, 6B, 7A, 7B, 11A, 11B, 12A and 12B are not described in the section of the specification.

Double Patenting

9. Claim 32 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,955,074. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims are directed to a species of method of treating Staphylococcus epidermidis infection, the immunoglobulin being selected against S.epidermidis teichoic acid antigen (see col. 6, lines 40-54) and the instantly claimed invention is directed to methods of treating any gram positive infection. A species anticipates the instantly claim genus.

Claim Rejections - 35 U.S.C. § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 32-40, 42-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment and prevention of infection caused by Gram positive bacteria with a polyclonal antibody to Gram positive lipoteichoic acid obtained from Staphylococcus, or with a monoclonal antibody MAB96-110, does not reasonably provide enablement for the utilization of any monoclonal, fragment, region or derivative of an antibody that binds to SEQ ID No 1 or 2, or is a derivative of SEQ ID NO 88 or 89, for the treatment or prevention of Gram positive bacterial infection. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification teaches a specific monoclonal antibody designated MAB 96-110, and teaches the production antigen binding regions thereof, as well as discloses polyclonal antibodies that bind to lipoteichoic acid components of Gram positive bacteria for treatment and prevention of infection, but the instantly claimed invention is not enabled for the utilization of any antibody, fragment, region, or derivative of any polyclonal or monoclonal antibody for treating or prevention infection caused by any Gram positive bacteria in light of the unpredictability of antibodies known in the art.

Fiedel et al (1972, abstract title) found anti-teichoic acid antibodies to induce kidney disease in rabbits. Clearly these antibodies to teichoic acid did not treat or prevent infection but caused disease.

Aasjord, P et al (1985, abstract) discloses two monoclonal antibodies that specifically bind to staphylococcal lipoteichoic acid, which evidenced the equivalent binding specificities as antibodies associated with multiple sclerosis patients. All antibodies that bind to lipoteichoic acid epitopes would not provide means to prevent or treat any disease associated with a gram positive bacteria, because some antibodies are associated with pathological processes that are not preventative or therapeutic, but could cause undesirable physiological effects associated with multiple sclerosis.

Stashenko, P et al (1986, abstract) showed 5 monoclonal antibodies directed against streptococcus mutans lipoteichoic acid(LTA) which were not able to prevent adherence of Streptococcus mutants, S. salivarius, Ssanguis or L.casei from attachment, but enhanced adherence by 150-300 per cent. The antibodies did not function to prevent infection but enhanced the first step toward infection and disease, specifically bacterial adherence. The epitope to which the antibodies bound was a polyglycerol phosphate portion of the LTA molecule.

Wergeland et al (1989, abstract) teach that patients with staphylococcal infections have antibodies to peptidoglycan, teichoic acid and lipoteichoic acid in their sera, but still have disease. The antibodies to lipoteichoic acid and the antigenic components thereof, were not protective antibodies. All antibodies that specifically bind to lipoteichoic acid and fragments thereof, are not protective or preventive antibodies.

Yuji et al (1995, abstract, title) teach children with serum anti-lipoteichoic acid antibodies still evidence recurrent tonsillitis. The anti-lipoteichoic antibodies were not protective antibodies to prevent or treat infection.

Clearly, the prior art teaches that polyclonal antibodies and monoclonal antibodies that specifically bind to gram positive bacterial lipoteichoic acid that do not provide protection against infection, and are not useful for preventing or treating disease caused by gram negative bacteria.

With respect to antibodies that bind to the peptide of SEQ ID NO 1, an antibody would not necessarily be specific for a gram ~~negative~~ positive bacterium in light of amino acids 3-7 share 100% sequence identity with a T-cell surface glycoprotein CD8 alpha chain precursor (Accession number P30433); Caenorhabditis elegans (accession number T22156) comprising a sequence that shares 100% sequence identity with amino acids 7-11; Brandyrhizobium japonicum sharing 100% sequence identity with amino acids 10-14 (accession number S39402), Arabidopsis thaliana sharing 100% sequence identity with amino acids 10-15 (accession number A71447);, thus an antibody directed to and evidencing binding specificity to any portion of SEQ ID NO 1 would not necessarily evidence gram positive bacterial infection associated binding specificity.

With respect to the recitation of SEQ ID No 2 to define the synthetic peptide of claims 36-37, antibodies that bind to this peptide would not by specific for gram ~~negative~~ positive bacterial infections, because monoclonal antibodies that bind this exact sequence are associated with Toxoplasma gondii, a eukaryotic parasite (100% sequence identity with SEQ Id No 2; EP724016, 1996). Additionally this peptide has been shown to be associated with an antibody for the inhibition of cancer metastasis (JP10237099, 1998) and an Fc domain that is useful in the

treatment of cancer, asthma, thrombosis and autoimmune disease. Clearly antibodies that bind SEQ ID No 2 peptide or a fragment (Fc fragment) thereof would not lack disease association specificity for gram positive bacteria in light of the antibodies or fragments would bind to a parasite, cancer associated sugars chains, and autoimmune disease associated components.

Additionally with respect to peptides that are encoded by DNA that shares "at least 70% homology" with SEQ ID NO 88 or 89 as shown in Figure 12, it is clear from the sequence search that there are numerous monoclonal chimeric light chains known in the art that share more than 70% amino acid sequence identity with SEQ ID No 89, or SEQ ID No 88 and do not evidence binding characteristics for gram positive bacteria, but evidence binding for blood Factor IX or an antiidiotypic antibody (see accession numbers AAW24532, PL0082, and X58586).

The prior art supports the fact that antibody compositions, whether polyclonal or monoclonal, would unpredictably treat or prevent gram positive bacterial infection. While Dale et al showed anti-lipoteichoic acid antibodies when administered to the nose of a host were able to prevent infection, the references cited above showed monoclonal and polyclonal antibodies which were not shown to evidence binding specificities that result in treating and preventing gram positive infection. The route of administration, the concentration of antibodies, the binding specificity and the animal to which the antibodies are administered clearly effect the positive or negative outcome when antibodies are used in a method that comprises the step of administering a composition to a patient.

No specific guidance has been provided as how to modify any antibody region, or derivative, or how to use any antibody fragment as a pharmaceutical composition to provide a therapeutic or prophylactive effect directed against any and all gram positive bacteria. While antibodies could be screened for binding specificities to lipoteichoic acid, epitopes that differ from that which has been shown to be protective, and recited in the claims (Mab 96-110) would not predictably define a composition that would be therapeutic or preventive for gram positive bacterial infection. Only monoclonal antibody Mab 96-110 has been shown to predictably

provide a positive effect in vivo and would function in the claimed method, but not the full scope of the instantly claimed invention.

The specification does not provide substantive evidence that all antibody compositions that comprise antibodies to lipoteichoic acid would function as vaccines capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed pharmaceutical composition (vaccines) for their intended purpose of preventing or treating gram positive bacterial infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration, i.e. would not be able to accurately predict if protective immunity has been induced in light of the prior art showing that antibodies that bind to lipoteichoic acid do not evidence protective characteristics for gram positive bacteria simply based upon antigen binding specificity. It would require undue experimentation given the fact that the specification is completely lacking in teachings how to obtain antibodies, antibody fragments, regions or derivatives of antibodies, derivative of fragments, and derivative regions with the desired protective binding characteristics in light of the anti-teichoic acid antibodies not predictably providing the desired effect without prior evaluation.

13. Claims 32, 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 37 recites the phrase "an antibody to lipoteichoic acid of Gram positive bacteria, or fragment, region or derivative thereof". While the antibody is defined to be a lipoteichoic acid binding antibody, the "fragment, region or derivative thereof" is a phrase that can modify the antibody, the bacteria or the lipoteichoic acid. What the binding specificity of the antibody is, is unclear in light of the word "thereof" referring back to possibly more than one molecule. This rejection could be obviated by amending the claim to recite --of said antibody--.

Claim Rejections - 35 U.S.C. § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Please Note case law applicable to following prior art rejections.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

15. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Dale et al (1994, abstract).

Dale et al disclose the claimed invention directed to a method of preventing infection, the method comprising the step of :

administering a pharmaceutical composition that comprises an antibody to lipoteichoic acid of a gram positive bacteria (see abstract).

The antibodies prevented infection upon challenge with a gram positive bacteria; colonization was not established thus defining an antibody that binds twice background (background being zero). Opsonization of the Gram positive bacteria resulted in no colonization defining the administered composition to evidence at least 75%, and more likely 100% Opsonization in light of no colonies became established. The reference anticipates the instantly claimed invention.

16. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (WO93/19373).

Fischer discloses the claimed method, the method comprising the step of:

administering to a patient a therapeutically or prophylactively effective amount of a pharmaceutical composition, the composition comprising antibodies to Gram positive bacteria (see claims 27 and 28, and all figures).

17. Claims 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Fattom et al (US Pat. 5,770,208).

Fattom et al disclose the claimed method, the method comprising the step of:

administering to a patient a therapeutically or prophylactively effective amount of a pharmaceutical composition (see abstract, and claims 19-23), the composition comprising antibodies (to Gram positive bacteria, wherein the antibodies are polyclonal or monoclonal antibodies and react with a conserved sugar and two other polysaccharide antigens. The reference anticipates the instantly claimed invention.

18. Claims 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Gristina et al (US Pat. 5,505,945).

Gristina et al disclose the claimed method, the method comprising the step of:

administering to a patient a therapeutically or prophylactively effective amount of a pharmaceutical composition (see Table 6, title, abstract, col. 9, lines 44-49; col. 13, lines 1-14; claims 2, and 4,), the composition comprising antibodies to Gram positive bacteria, wherein the antibodies are polyclonal or monoclonal antibodies and prevent adhesion of the pathogens to a surface associated with disease (see col. 8, lines 64-67). The reference anticipates the instantly claimed invention.

19. Claims 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Fattom et al (WO93/09811).

Fattom et al disclose the claimed method, the method comprising the step of:

administering to a patient a therapeutically or prophylactively effective amount of a pharmaceutical composition (see page 13, lines 15-21; page 14, lines 22-24), the composition comprising antibodies (to Gram positive bacteria, wherein the antibodies are polyclonal (see page 7, lines 1-4; lines 18-29; page 9, lines 20-28; affinity purified: page 9, lines 29-38; Fab fragments see page 12, lines 25-38) or monoclonal antibodies (see page 9, lines 1-10; pages 10-11; Example 8, page 19) and would react with amino acids and sugars that are shared by both the capsular serotype antigen and lipoteichoic acid, the polysaccharide component being referred to as serotype I and II antigen (see page 5, lines 3-6). The reference anticipates the instantly claimed invention.

20. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Ichiman et al (1989)

Ichiman et al discloses the claimed method, the method comprising the step of:

administering to a patient a therapeutically or prophylactively effective amount of a pharmaceutical composition, the composition comprising antibodies to Gram positive bacteria, that are unencapsulated, thus comprising antibodies to cell surface teichoic acid antigens (see page 283, paragraph 1). The reference anticipates the instantly claimed invention.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

22. Endl et al (1983) is cited to show the cell wall teichoic acid chemical composition for staphylococci.
23. Gristina et al (US Pat. 5,707,627) is cited to show antibodies and methods for passive immunization directed against coagulase negative bacteria, S.aureus and S.epidermidis (see all claims).
24. Ichiman et al (1981, Journal of Applied Bacteriology) is cited to show biochemical analysis of cell surface polysaccharides to be composed of hexosamine, glycerol, phosphorous, alanine, glycine and phenylalanine.
25. JP 01226828A (English abstract) is cited to show antibodies to lipoteichoic acid, and polysaccharide for the prevention of dental caries.
26. Pavliak et al (US Pat. 6,355,625) is cited to show hyper immune antibody compositions specific for S.epidermidis and S.aureus used in a method of treating or preventing infection (see coll 2, lines 22-67; col. 4, lines 14-22).
27. Rogers et al (US Pat. 5,069,896) is cited to show monoclonal antibodies directed against a Staphylococcal cell surface transport protein and a method of use to prevent malodor expression.
28. Shockman et al (US Pat. 4,596,769) is cited to show monoclonal antibodies that specifically bind to peptidoglycan of eubacteria, which includes staphylococcus, streptococcus and bacillus bacteria (see col. 2, lines 37-54) and suggests the utilization of the antibodies for therapeutic purposes (see col. 13, lines 3-7).
29. Stephan et al (US Pat. 4,965,068 and 4,318,902) are cited to show polyvalent hyper immunoglobulin for the treatment of Streptococcus infection.
30. Stolle et al (US Pat. 4,732,757 and RE33,565) are cited to show methods and compositions for prevention and treatment of gram positive infection (see all claims).
31. Yoshida et al (1988) is cited to show that the cell surface polysaccharide was found to contain a significant about of teichoic acid (see page 497, col. 2).
32.Espersen et al (1981) is cited to show analysis of S.epidermidis peptidoglycan and teichoic acid to determine some of components (see page 258, col. 1, Discussion section, paragraphs 2-4).

33.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
January 8, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600